



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-1105]

Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations:

Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers.” The draft guidance provides information for sponsors, clinical investigators, institutional review boards (IRBs), contract research organizations (CROs), and other interested parties on the use of electronic systems, electronic records, and electronic signatures in clinical investigations of foods, medical products, tobacco products, and new animal drugs under FDA regulations. This draft guidance revises the draft guidance for industry issued in June 2017 entitled “Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11--Questions and Answers” and, when finalized, will supersede the guidance for industry entitled “Computerized Systems Used in Clinical Investigations” (May 2007).

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-D-1105 for "Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

<https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001

New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002; or Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Kunkoski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3332, Silver Spring, MD 20993-0002, 301-796-6439, Elizabeth.Kunkoski@fda.hhs.gov; Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911, Diane.Maloney@fda.hhs.gov; Soma Kalb, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G318, Silver Spring, MD 20993-0002, 301-796-6539, Soma.Kalb@fda.hhs.gov; Yuguang Wang, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., Rm. 4A-012, College Park, MD 20740, 240-402-1757, Yuguang.Wang@fda.hhs.gov; the Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Silver Spring, MD 20993-0002, 240-402-7970, CTP-BIMO@fda.hhs.gov; or Eric Nelson, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., MPN #4, Rm. 106, HFV-230, Rockville, MD 20855, 240-402-5642, Eric.Nelson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions

and Answers.” The draft guidance provides information for sponsors, clinical investigators, IRBs, CROs, and other interested parties on the use of electronic systems, electronic records, and electronic signatures in clinical investigations of foods, medical products, tobacco products, and new animal drugs. The goals of the draft guidance are to (1) update recommendations for applying and implementing data integrity and data security controls, including the use of audit trails and the protection of records in the current environment of electronic systems used in clinical investigations; (2) provide additional recommendations on the risk-based approach to validation of electronic systems described in the guidance for industry “Part 11, Electronic Records; Electronic Signatures--Scope and Application” (August 2003); and (3) facilitate the use of electronic systems, electronic records, and electronic signatures to improve the quality and efficiency of clinical investigations.

In the *Federal Register* of June 21, 2017 (82 FR 28277), FDA announced the availability of the draft guidance entitled “Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11--Questions and Answers.” FDA received numerous comments on the draft guidance, and those comments were considered as the guidance was revised. A summary of changes includes clarifying recommendations for the following: (1) using a risk-based approach for validation of electronic systems used in clinical investigations; (2) preparing for FDA inspections of sponsors and CROs when electronic systems are owned, controlled, or outsourced by the sponsors and CROs for use in clinical investigations; (3) implementing, maintaining, and retaining audit trail information; (4) determining the suitability of information technology (IT) service providers contracted by sponsors or other regulated entities to provide IT services in clinical investigations; and (5) implementing and applying data integrity controls, data security solutions, and electronic source data principles to digital health technology used in clinical investigations. This guidance revises the draft guidance issued in June 2017 and, when finalized, will supersede the guidance for industry entitled “Computerized Systems Used in Clinical Investigations” (May 2007).

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by the OMB under the PRA. The collections of information in 21 CFR part 11 have been approved under OMB control number 0910-0303; the collections of information in 21 CFR part 56 have been approved under OMB control number 0910-0130; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; the collections of information in 21 CFR part 511 have been approved under OMB control number 0910-0117; and the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance>, <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>,

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or

<https://www.regulations.gov>.

Dated: March 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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